

Rapid HIV-1 Antibody Testing during Labor and Delivery for Women of Unknown HIV Status

(condensed from original article available at http://www.cdc.gov/hiv/rapid_testing/rt-labor&delivery.htm)

Tremendous medical and public health achievements have been made in the prevention of mother-to-child transmission (MTCT) of HIV-1. The risk for infant infection has been reduced from approximately 25% to less than 2% by the use of currently recommended prenatal antiretroviral (ARV) and obstetric interventions for a woman who is aware of her HIV infection early in pregnancy. Pregnant women who are HIV infected but who do not receive prenatal care or do not receive an HIV test during prenatal care are not identified as HIV infected and therefore miss opportunities to reduce the risk of transmission to their infants and to receive life-saving treatments for themselves.

The Centers for Disease Control and Prevention (CDC) recommends routine rapid HIV testing using an opt-out approach for women in labor whose HIV status is unknown. Routinely offering rapid HIV testing in a point-of-care setting to women whose HIV status is unknown during labor and delivery provides the opportunity to reduce transmission even among women who do not seek care until labor begins. The rapid HIV test kits now licensed in the United States allow test results to be available in 20 minutes or less. Results from the OraQuick® Rapid HIV-1 Antibody Test (OraSure Technologies, Inc., Bethlehem, Pennsylvania) can be read within 20–40 minutes. Other rapid test kits are also available.

Offering point-of-care testing requires training and continual supervision to ensure competent and proficient testing. This requirement can pose a challenge, especially if staff turnover is high. When rapid testing is performed in the laboratory, attaining consistently prompt results requires the availability of 24-hour staff responsive to the urgent need for immediate HIV test results. The College of American Pathologists Commission on Laboratory Accreditation has published a point-of-care testing checklist, which is used as part of its accreditation process. The checklist, which may help to guide the point-of-care testing process in labor and delivery settings, is available at:

http://www.cap.org/apps/docs/laboratory_accreditation/checklists/point_of_care_testing_december2003.pdf

A concern of facilities offering rapid HIV testing may be the accuracy of the tests. The accuracy of diagnostic tests is expressed in terms of sensitivity and specificity, as well as the positive and negative predictive value of the test result. No test is both 100% sensitive (no false-negative test results) and 100% specific (no false-positive test results). Screening tests are designed to be highly sensitive to ensure that no infected person is missed. The price for this high sensitivity is a slightly reduced specificity, that is, some women who are not infected with HIV will have false-positive HIV screening test results.

Provisions, therefore, must be made to confirm all preliminary positive rapid HIV test results, as soon as possible, with a supplemental test such as the Western blot or immunofluorescent assay (IFA). However, such testing can take several days or more and does not satisfy the need for timely HIV test results for women in labor. Thus, even in optimal rapid testing programs, some women who are not infected will receive ARV prophylaxis on the basis of a false-positive result from a rapid HIV test. The seriousness of the psychological effect of such a result is self-evident. However, a short course of the ARV prophylaxis currently recommended by the US Public Health Service has no known long-term safety effects for women and infants who are not infected.

Observational studies and clinical trials have shown that when ARV prophylaxis is administered during labor or within the first 12 hours after birth, the risk of perinatal HIV transmission is reduced from 25% to 9%–13%.²⁻⁶ In addition, diagnosing HIV infection during labor and delivery provides a window of opportunity to offer infected women referral and treatment for their own care.

Experience at several hospitals has shown that HIV testing has often been done during the prenatal period but that results have not been available to labor and delivery staff. The lack of access to prenatal test results thus leads to unnecessary rapid testing and increases the potential for false-positive results and unnecessary ARV prophylaxis. During planning for the implementation of a protocol for rapid testing during labor, it is critical to ensure that all results of HIV testing during pregnancy are documented in the woman's prenatal record and readily available to labor and delivery staff. Ensuring the availability of prenatal results may require coordination with other antenatal health care facilities to make sure that the pregnant woman signs a medical release and that her prenatal records are routinely and promptly transferred to the delivery facility before the woman's due date.

Whether or not point-of-care testing is performed, labor and delivery staff will be called upon to provide women in labor whose HIV status is unknown with information on the availability of rapid HIV testing and perinatal HIV prevention and also to inform them that they will be tested unless they decline.

The prenatal records of all women presenting to the labor and delivery unit should be reviewed for documentation of an HIV test result during the current pregnancy. Any woman without documentation of an HIV test result during the current

pregnancy should be routinely screened for HIV by the use of a rapid HIV test and an opt-out. Including a standing order (e.g., “provide routine rapid HIV testing if there is no documentation of prenatal HIV test results unless the woman declines”) as part of the admission orders for women in labor may also save valuable time. CDC recommends routine rapid HIV testing for women in labor whose HIV status is unknown (women with no documentation of a prenatal HIV test in their medical records) unless they decline testing, that is, unless they opt out (CDC, Dear Colleague Letter, April 22, 2003; available at: <http://www.cdc.gov/hiv/PROJECTS/perinatal/2003/letter.htm>).

Protecting the confidentiality of the pregnant woman who receives HIV testing during labor is required both by ethical standards and legal requirements. However, in the busy and complex labor and delivery unit, maintaining confidentiality requires that staff members be knowledgeable and vigilant.

All efforts should be made to determine a mother's HIV status as soon as possible during labor. If the mother's HIV status remains unknown at delivery, she or the infant or both should have rapid HIV testing as soon as possible postpartum. When the rapid HIV test is discussed, the woman should be told how soon to expect the results. Usually, test results will be available before delivery and are given to the woman during labor, at which time she is asked to consent to antiretroviral prophylaxis if the preliminary result is positive. A woman may state that she doesn't want to be told the result of the rapid HIV test until after the baby's birth. In such an instance, consent for the initiation of prophylaxis should be obtained when testing is discussed. If possible, the clinician who discussed the HIV test should give the results. Privacy during the discussion of test results is essential to ensure confidentiality. The woman's physical comfort should be assessed and monitored while she is being given test results.

Results, whether positive or negative, should be given as soon as possible. If the rapid test result is negative, no further medical intervention is necessary. The woman should be told that she is most likely not infected with HIV but that the test may not show recent infection. The clinician should ask whether she is concerned about any recent specific risk of exposure; if she is concerned, the clinician should recommend retesting after 3 months if indicated. More extensive HIV counseling should be set up for her during the postpartum period, and she should be told of these arrangements.

If the rapid test result is positive, the clinician should tell the woman that she is likely to have HIV infection and that the baby may be exposed to HIV. She should be assured that a second test is being done right away to confirm the rapid test result but that the results will not likely be available before delivery. The clinician should explain that the rapid test result is preliminary and that false-positive results are possible but that it would be best to start ARV prophylaxis as soon as possible to reduce the risk of HIV transmission to the baby. The medication regimen that will be offered to the woman and her baby should be explained, including the known effects and possible adverse effects, and she should be given the opportunity to ask questions before accepting it. She should also be told to postpone breastfeeding until the confirmatory results are available because she should not breastfeed if she is HIV infected. The clinician should explain that all ARV prophylaxis will be stopped if the confirmatory test result is negative.

Preliminary results may not be available before delivery if labor is rapid or the woman is admitted to the unit late in labor. If the preliminary HIV test result is positive, ARV prophylaxis for the neonate should be initiated as soon as possible.

There are several ARV medications that can be used during labor and delivery as well as postpartum for the neonate. The US Public Health Service Perinatal HIV Guidelines Working Group publishes Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1–Infected Women for Maternal Health and to Reduce Perinatal HIV-1 Transmission in the United States. The recommendations are available as a living document (frequently updated) at www.aidsinfo.nih.gov/guidelines/.

Given the potential complexity of the clinical management decisions, it is strongly encouraged that local protocols for peripartum intervention for women whose HIV infection is diagnosed during labor be developed in consultation with HIV/infectious disease experts.

The routine use of rapid HIV testing and medical interventions in labor and delivery settings provides a final opportunity to reduce the effect of those missed opportunities for prevention. It is recommended that **hospitals adopt a policy of routine rapid HIV testing by using an opt-out approach for women whose HIV status is unknown when presenting to the labor and delivery**. It is recognized that implementing rapid testing programs in labor and delivery settings poses challenges. However, clinicians in labor and delivery settings frequently make complex medical decisions, implement emergency life-saving interventions, and discuss sensitive and difficult personal information with patients. This document is intended to assist clinicians by adding another important tool to their repertoire of clinical screening and HIV prevention interventions.